MITCH McCONNELL
KENTUCKY

COMMITTEES:
AGRICULTURE
APPROPRIATIONS
ENVIRONMENT AND PUBLIC WORKS
RULES
ETHICS (CHAIRMAN)

United States Senate

WASHINGTON, DC 20510–1702
(202) 224–2541

January 25, 1996

The Honorable Charles A. Bowsher
Comptroller General
General Accounting Office
441 G Street, NW, Room 7100
Washington, D.C. 20548

Dear Mr. Bowsher:

As you know, the Senate Appropriations Subcommittee on Agriculture, Rural Development, and Related Agencies has jurisdiction over the Food and Drug Administration (FDA). As a member of that Subcommittee, I have repeatedly and unsuccessfully attempted to obtain information from the FDA regarding its expenditures on a plan to assert jurisdiction over tobacco products.

The FDA has failed to fully or adequately comply with my requests for information, thus compromising the Subcommittee's ability to perform its program oversight responsibilities and, in effect, challenging the authority of the Senate. What is most disturbing is that on August 11, 1995, while continuing to disregard my requests, the FDA proposed sweeping new regulations over cigarettes and smokeless tobacco.

My request is twofold. First, I ask that GAO investigate the FDA's failure to comply with my multiple requests for financial information pertaining to this issue. GAO should determine:

a. how my requests were handled;
b. whether any documents or information were withheld from the Subcommittee;
c. if documents were withheld, who made the decision to withhold the information or records and the rationale for that decision; and
d. all documents, memoranda, and notes (including electronic messages) pertaining to my request.

Second, I request that the appropriate GAO division review and report on the appropriated monies spent by the FDA in connection with its proposed regulation of tobacco products. The intent of the report is to aid the Subcommittee in assessing:

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241 MAIN STREET
ROOM 102
BOWLING GREEN, KY 42101
(502) 781-1673

1885 DIXIE HIGHWAY
SUITE 345
FORT WRIGHT, KY 41011
(606) 578-0188

155 EAST MAIN STREET
SUITE 210
LEXINGTON, KY 40507
(606) 252-1781

1501 SOUTH MAIN STREET
SUITE N
LONDON, KY 40741
(606) 864-2026

601 WEST BROADWAY
SUITE 630
LOUISVILLE, KY 40202
(502) 582-6304

IRVIN COBB BUILDING
608 BROADWAY
PADUCAH, KY 42001
(502) 442-4554

a. how much money was and will continue to be spent by the FDA on this non-core activity; and
b. the diversion of appropriated monies and resources from the core activities of the Agency.

My concern is not just this specific regulation, but the time, effort and tax dollars FDA expended in developing such a far-reaching regulation--and the burden it placed on the FDA's other, core activities.

I request that your investigation include answers to questions I have previously asked of FDA, which are attached. Also enclosed are copies of documents previously transmitted between the FDA and me.

Given that the Senate Appropriations Committee will soon begin its work on the FY 1997 appropriations bills, I ask that this report and investigation commence and be completed as soon as possible. Specifically, I would like a final report completed by March 1, 1996. Thank you for your assistance.

Sincerely,

MITCH McCONNELL
UNITED STATES SENATOR

Enclosure

MM/dh

CC: Honorable Thad Cochran

1. What was the amount of appropriated monies spent by or on behalf of the FDA on the tobacco products investigation and proposed rulemaking in FY 1994, FY 1995, and FY 1996?

2. State the budgeted and/or expected amount of appropriated monies to be spent on the proposed rulemaking through FY 1997?

3. State the estimated number of employees and any other persons (including any private individual or organization) and the amount of appropriated monies necessary to implement and enforce the proposed regulations, if adopted in their current form.

4. State the number of employees, detailees, or consultants currently working, in any form or manner, on the proposed rulemaking. How many will continue working on this regulation through FY 1997?

5. State FDA's timetable for completion of review of the public comments submitted for the proposed regulation and expected date of publication of the final regulation.

6. State the number of FDA employees involved in the investigation of tobacco and related issues including formulation of the proposed rulemaking in FY 1994, FY 1995, and FY 1996.

7. State what division those employees are assigned to for budgetary purposes (stating specifically how many employees were used from each division) and other responsibilities of these individuals within the Agency.

8. List each employee, consultant, detailee, or any other person (including any private individual or organization) who contributed in any manner to the investigation, development of the proposed rule (including reviewing and/or responding to public comments received by the Agency) and analysis issued by the FDA on August 11, 1995. Describe the contribution of each and the remuneration provided, if any. Include in the list any individual who provided suggestions on how to structure the proposed rule.